Friday, January 16th, 1998

Dockets Management Branch [HFA-305]
Food and Drug Administration
12420 Parklawn Drive
Room 1-23
Rockville MD 20855

To Whom it May Concern:

Comments on the discussion draft on proposals to increase availability of approved Animal Drugs for Minor Species & Uses

I would like to reply to your agency's request for comments and suggestions on the above draft dated December 19th, 1997. I note that several of my comments in my original comments of last September are reflected in the discussion draft and I would remind you that I am a veterinarian employed at a College of Veterinary Medicine and the Southern Drug Coordinator in the NRSP-7 program. The views I am expressing here are my own and do not necessarily reflect those of my Institution or of the NRSP-7 program.

In September I wrote that any changes in the approval process should not create second class drugs with inferior background. My major dissension from the draft is proposal H that proposes lesser standards for minor species/uses approval. I believe that if approval is so needed then the conditional route would be preferable in providing immediate relief to new and urgent problems while providing strong incentive to complete the approval packet.

Taking the other sections I would comment generally that the financial gain to a sponsor should be specific and not aimed at increasing profit hoping it will be invested in supplemental work. I am an idealist but enough of a realist to believe such undirected incentives are a waste of tax-payer's money. Modifications to extralabel restrictions (A) seem duplicative of G [conditional approvals]. I would prefer the stronger incentive to develop data towards an INAD be used as the carrot.

All of the suggestions for removal of disincentives (B) seem very timely and would be productive. Obviously in discussing increased funding for existing programs I have a conflict of interest but still favor increased funding and function of the NRSP-7 program. In fact that group is already proposing such changes in it's renewal package currently being prepared. The panel of outside reviewers appointed by the USDA to critique the program has also advocated

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this. I think development of other programs based on the NRSP-7 model would be duplicative and, without FDA input/association, would be less effective and may lessen the impact of the original NRSP-7 project. The establishment of a minor species database in the FDA with a dedicated FTE seems wasteful and lacking clear definition.

Incentives are obviously needed but I cannot agree with the concept of increasing income on major claims to perhaps spur minor species work as noted above. The exclusivity increases and tax credits seem to lead one to an orphan drug program clone. As I stated in September, I am very much in favor of giving manufacturer's residue work "significant new data" status although I think it important that such data be freely available to accepted residue database groups for use in advice and analytic development. [Here, as a .FARAD director I must declare a possible conflict of interest].

From earlier comments, I can be correctly predicted as being as favoring statutory category of minor use animal drugs (F)

I am not certain how to interpret the conditional approval as regards to the different levels of concern (G). I think if human safety is protected by use of robust withdrawal times and knowledge of a drug's pharmacodynamics to allow evaluation of the human toxicity risk, even food animals should be allowed to benefit from this concept. I think the safeguard limitations suggested in the draft would be essential in allowing this flexibility.

Yours truly,

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